

Mr. & Mrs. H. Horejsi
3630 Callan Blvd.
South San Francisco, CA 94080
May 23, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

Re: F.D.A. Docket No. 98N-1265

We would herewith like to register our concern and extreme DISAPPROVAL of the Memorandum of Understanding (MOU) as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of physicians and patients to obtain healthcare products from the provider of their choice, and infringes on the rights of compounding pharmacists to serve the public's medical needs. You are trying to circumvent medical practitioners from prescribing what they believe is best for their patients and to severely limit the practice and interstate distribution of compounded drugs. Many people involved in drafting the original legislation, who are familiar with the Modernization Act of 1997, feel that the MOU drafted by the FDA does not accurately represent the original intent of Congress. The MOU places unnecessary restrictions on consumer choices and commonly accepted professional pharmacy compounding practices.

Your job is to be the watchdog for consumer safety. THIS IS NOT A SAFETY ISSUE!! This proposed new "legislative guidance" is nothing more than the usual strong-arm tactics of the FDA to impose your will on healthcare professionals who advise their patients of alternative compounds to those that are generally prescribed. It is imperative that there be no restrictions to the delivery of a compounded medication prescribed to us by our physicians, regardless of where we may live. For the most part, these compounded medications are paid for by the patients themselves as insurance companies will not reimburse for medications that are not in their "formularies" which consist ONLY of patented drugs.

Many individuals have difficulty with or toxic reactions to patented (i.e. non-compounded) drugs. With the MOU, the FDA would restrict the options if the drug is not compounded in their state, and if one travels across state lines, one may also not be able to order the drug and have it shipped to one's home address.

You are DISCRIMINATING by singling out compounded drugs and not also doing so for non-compounded (patented) drugs, and that is illegal. You are also taking away consumer choice, but most of all, you are meddling in the doctor/patient relationship which you have no business in doing.

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We demand you leave this subject alone and let the doctors/pharmacists decide what's best for their patients.

Yours truly,

Charles + Herbert Hoggis

CC: Rep. Tom Lantos
Senator Dianne Feinstein
Senator Barbara Boxer
Senator Orrin Hatch

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